Comparison of the Outcome of Administration of Tranexamic Acid During Percutaneous Nephrolithotomy at Tertiary Care Hospital

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Abstract

Objective: To evaluates the safety and effectiveness of TXA in minimizing blood loss and transfusion needs during PCNL.

Material and Methods: A Quasi-Experimental Design was conducted at Liaquat University of Medical and Health Sciences, Jamshoro, from October 1, 2023, to March 31, 2024, including 96 PCNL patients. Participants were assigned to either the TXA group (1g intravenous TXA, 20 minutes preoperatively) or the placebo group (10 cc normal saline), each with 48 patients. Blood loss was assessed via perioperative hemoglobin levels and irrigation fluid volume. Transfusion needs, operative time, and patient demographics were analyzed using SPSS version 16, with a p-value ≤ 0.05 considered significant.

Results: TXA significantly reduced blood loss (75.38 ± 59.29 mL vs. 113.57 ± 82.36 mL; p=0.001) and transfusion rates (16.7% vs. 20.8%; p=0.01). Operative time and obesity influenced transfusion needs, but TXA consistently reduced blood loss across subgroups. No significant thromboembolic complications were observed.

Conclusion: TXA effectively reduces blood loss and transfusion requirements during PCNL without increasing adverse events, making it a valuable adjunct in high-risk patients. Further studies are needed to standardize dosing and assess long-term outcomes.

Keywords: Percutaneous nephrolithotomy, Tranexamic acid, Surgical bleeding, Blood loss, Transfusion requirements, Urological surgery

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Introduction

Percutaneous nephrolithotomy (PCNL) is a well-established surgical procedure that may remove large or difficult renal calculi. Due to its high success rate and minimally intrusive nature, treating significant kidney stone loads has become routine therapy. Together, these two causes create this. This is because these two important features are together. PCNL has many benefits, but perioperative blood loss can lead to blood transfusions, lengthen hospital stays, and increase the risk of postoperative complications. The specific situations have highlighted the need for ways to reduce bleeding and enhance patient outcomes.

Percutaneous nephrolithotomy (PCNL), a crucial kidney stone treatment, is suitable for large or difficult stones. Skin-based PCNL targets the kidneys. This applies to stones larger than two

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centimeters or those with anatomical anomalies [1]. Create a percutaneous conduit to the renal pelvis to remove stones using nephroscopic equipment. Current knowledge suggests this surgery is less invasive. PCNL's most concerning consequence is perioperative bleeding. Many additional issues are linked to PCNL. Despite being an effective approach, PCNL has drawbacks. Percutaneous nephrolithotomy (PCNL) may lose 100 to 1,000 milliliters of blood, according to study. Five to twenty percent of patients require blood transfusions [2]. Excessive blood loss complicates surgery and increases the risk of transfusions, infections, and long recovery. Generally, complications grow. This has highlighted the necessity for bleeding-reducing medications.

Tranexamic acid (TXA), a synthetic antifibrinolytic medication, has gained popularity in recent years owing to its ability to reduce surgical bleeding. TXA works by restricting plasminogen activation to plasmin. This inhibits fibrinolysis and stabilizes clots [3]. This product has been extensively researched and recommended for use in several surgical specialties. It reduces blood loss and transfusions in obstetrics, cardiac, and orthopedic surgery [4]. However, its utility in urological procedures, such as PCNL, is still being researched using this approach. Transcranial ultrasonography (TXA) may minimize bleeding and enhance surgical outcomes in PCNL [5]. Preliminary research suggests this may be true.

TXA in PCNL raises concerns regarding thromboembolic complications, particularly in at-risk patients, requiring additional investigation. TXA may cement blood clots, which might induce thrombosis. This is why a thorough TXA safety study in high-risk populations is crucial [6]. Even though TXA is deemed risk-free, certain ailments may nonetheless develop. Also disputed are dosage changes, administration timing, and patient selection criteria. Clinical research is essential for developing standardized methods. Here's why.

This study investigates the effects of TXA administration on PCNL patients in tertiary care facilities. The research will fill the gaps. This study compares patients who receive transfusion-free airway (TXA) to those who do not to accurately assess surgical complications like thromboembolic events, perioperative blood loss, transfusion needs, and transfusion requirements. This research recommends TXA for PCNL clinical practice to improve patient safety and surgical outcomes. Evidence will underpin these notions.

Millions of individuals worldwide suffer from kidney stone illness. Urological conditions like kidney stone disease impact millions. Percutaneous nephrolithotomy (PCNL) is the preferred therapy for large or problematic kidney stones. Recent advances in less-invasive techniques may explain this. This method may remove several stones and recover faster than open surgery. However, excessive perioperative bleeding still affects surgical outcomes and patient recovery. Despite addressing this worry, this is true. The volume of blood lost during percutaneous non-surgical kidney (PCNL) treatments is calculated using many parameters. Stone size, patient comorbidities, and surgical technique are factors. However, this method may cause hypersensitive reactions, infections, and greater medical costs [7]. Some blood transfusions are necessary, but they include dangers. To limit blood loss and make PCNL safer for patients, viable solutions have been sought. This is due to difficulties raised.

Transexamic acid (TXA) may help with post-surgery bleeding. A possibility has been examined. Fibrinolysis is inhibited by TXA, a synthetic lysine derivative [8]. TXA is lysine-derived synthetically. Additionally, it promotes stable clots. Due to its use in obstetrics, cardiothoracic, and orthopedic surgery, it has been shown to significantly reduce blood loss during and after surgery and prevent thromboembolic events [9]. This proves the process works. Transurethral angioplasty (TXA) is limited in urology despite its potential. Especially in PCNL, bleeding must be reduced. Recent studies have indicated that TXA during PCNL may reduce transfusions and improve surgical outcomes [10]. Despite a data scarcity, the following occurs. This study aims to add to the growing body of information on optimizing renal stone disease surgery. A tertiary care institution will conduct a thorough research on transcatheter angioplasty (TXA) effectiveness and safety in PCNL to achieve this goal. This research seeks to determine if TXA is safe and acceptable for use. Tranexamic acid (TXA) has been demonstrated to reduce blood loss during several surgical procedures, although its utility in percutaneous nephrolithotomy (PCNL) remains unexplored. Despite its success in other surgeries. High-quality data is scarce in this setting, making it impossible to utilize consistently. Most PCNL TXA research has shown equivocal findings

on its efficacy and safety. Most of these studies are retrospective, small, or lack rigorous control groups. This is why. Concerns about thromboembolic consequences emphasize the need for large, well-planned Quasi-Experimental Design. The proper dose and duration of TXA are also unknown. Both of these criteria justify these experiments. Resolving these gaps will reveal how TXA improves PCNL surgical results. This is crucial when perioperative bleeding persists.

Material and Methods

This research was conducted as a quasi-experimental design at the Department of Urology, Liaquat University of Medical and Health Sciences (LUMHS), Jamshoro. Ethical approval was granted by the Ethical Review Committee (ERC) of Bilawal Medical College for Boys, LUMHS, Jamshoro, under the approval number ERC/BMC/36-2024. The study was carried out over a six-month period, from October 1, 2023, to March 31, 2024. A total of 96 participants were enrolled and equally distributed into two groups, with 48 patients in each group. The sample size was calculated using the OpenEpi sample size calculator, assuming a power of 80% and a confidence interval of 95%, based on previously reported mean blood loss values of 73.80 ± 60.1 mL and 117.24 ± 87.9 mL. A non-probability consecutive sampling technique was employed to ensure efficient recruitment of all eligible patients who met the inclusion criteria during the study period, thereby eliminating random selection bias.

Participants included patients undergoing percutaneous nephrolithotomy (PCNL) for renal stones measuring 2 cm or greater, including lower pole calculi with difficult anatomical access, multiple stones, or those resistant to extracorporeal shock wave lithotripsy (ESWL). Eligible individuals were between 20 and 45 years of age, of any gender, and had provided informed consent. Exclusion criteria included a history of thromboembolic disorders, single kidney, hematologic malignancies, anemia requiring transfusion or supplementation (such as iron deficiency anemia, vitamin B12 deficiency, megaloblastic anemia, or thalassemia), acute coronary syndrome, stroke, asthma, chronic obstructive pulmonary disease, chronic renal failure, or chronic liver disease.

All patients provided informed consent, and institutional ethical approval was obtained prior to the study. Participants were randomly assigned to two groups using sealed opaque envelopes: Group T received tranexamic acid and Group P received a placebo. The preparation of the drug and placebo was carried out by a pharmacist to maintain the integrity of blinding. Group T received a single intravenous dose of 1 gram of tranexamic acid 20 minutes before the procedure, while Group P was administered 10 cc of normal saline. All procedures were performed by a single experienced surgeon under either general or spinal anesthesia, depending on the patient's condition and preference. Each patient received one gram of cefuroxime as preoperative prophylaxis.

Blood samples were collected before surgery, immediately after the procedure, and again 24 hours postoperatively. Perioperative blood loss was calculated by measuring the volume of irrigation fluid and determining the hemoglobin concentration in the fluid collected through the nephrostomy tube. Additional data, such as transfusion requirements and demographic variables including age, gender, and residence status, were recorded using a structured proforma.

Statistical analysis was performed using SPSS version 16. Quantitative variables, including age, operative time, hemoglobin levels, and blood loss, were presented as means and standard deviations for normally distributed data, or as medians and interquartile ranges for non-normally distributed data. Categorical variables, such as gender, residence status, obesity status, and transfusion requirements, were expressed as frequencies and percentages.

Results

This Quasi-Experimental Design had 96 patients receiving percutaneous nephrolithotomy (PCNL), with 48 individuals allocated to each group. There was a balanced distribution of potential confounding variables since the clinical and demographic features of the two groups were similar. The effectiveness and safety of tranexamic acid (TXA) administration during PCNL were assessed by analyzing key outcomes, such as blood loss, transfusion requirements, and variables impacting transfusion needs. To find significant differences between the TXA and placebo groups, statistical analyses were

performed; a p-value of < 0.05 was deemed statistically significant. The specific results are shown below.

The demographic and clinical characteristics of participants in Group T (tranexamic acid group) and Group P (placebo group) were analyzed to ensure comparability. Regarding age distribution, the majority of participants in both groups were aged between 31 and 45 years, accounting for 62.5% in Group T and 64.6% in Group P. Participants aged 20 to 30 years comprised 37.5% of Group T and 35.4% of Group P, indicating similar age distributions across the groups. In terms of gender, Group T had a higher proportion of male participants (52.1%) compared to Group P (29.2%), while Group P had a significantly higher proportion of female participants (70.8%) compared to Group T (47.9%). This suggests a gender imbalance between the groups. The majority of participants in both groups were from urban areas, with 83.3% in Group T and 79.2% in Group P. Rural participants comprised 16.7% of Group T and 20.8% of Group P, indicating a slightly higher proportion of rural residents in Group P.

When comparing operative times, 43.8% of procedures in Group T and 39.6% in Group P were completed within 120 minutes, while 56.2% in Group T and 60.4% in Group P required more than 120 minutes. This reflects a similar distribution of procedural complexity between the groups. Regarding obesity status, 33.3% of participants in Group T were classified as obese compared to 43.8% in Group P, while the majority of participants in both groups were non-obese, with 66.7% in Group T and 56.2% in Group P. These findings suggest a slightly higher prevalence of obesity in Group P, which could be a potential factor influencing operative outcomes.Group T (tranexamic acid group) experienced a considerably lower mean blood loss during the operations than Group P (placebo group). Group P exhibited a significantly larger mean blood loss of 113.57 ± 82.36 mL than Group T, which had a mean blood loss of 75.38 ± 59.29 mL. With a p-value of 0.001, this difference was statistically significant. These findings imply that tranexamic acid treatment successfully lowers perioperative blood loss in individuals having percutaneous nephrolithotomy (PCNL). This demonstrates how adding tranexamic acid to clinical practice may help enhance surgical results and reduce the need for transfusions. Table 3 compares various factors that influenced transfusion requirements in both Group T (tranexamic acid group) and Group P (placebo group).

Table 1: *Demographic and Clinical Characteristics of Group T and Group P*

Variables	GROUP T	GROUP P
AGE (YEARS)		
20-30	18 (37.5%)	17 (35.4%)
31-45	30 (62.5%)	31 (64.6%)
GENDER		
MALE	25 (52.1%)	14 (29.2%)
FEMALE	23 (47.9%)	34 (70.8%)
RESIDENCE STATUS		
URBAN	40 (83.3%)	38 (79.2%)
RURAL	08 (16.7%)	10 (20.8%)
OPERATIVE TIME		
≤ 120 MINUTES	21 (43.8%)	19 (39.6%)
> 120 MINUTES	27 (56.2%)	29 (60.4%)
OBESITY STATUS		
YES	16 (33.3%)	21 (43.8%)
NO	32 (66.7%)	27 (56.2%)

Table 2: *Comparison of Mean Blood Loss Between Group T and Group P*

VARIABLE	GROUP T	GROUP P	P VALUE
MEAN BLOOD LOSS	75.38±59.29	113.57±82.36	0.001

There were no significant differences in transfusion requirements based on age groups. In Group T, 22.2% of participants aged 20-30 years and 13.3% of those aged 31-45 years required transfusions. In Group P, 29.4% of participants aged 20-30 years and 16.1% of those aged 31-45 years required transfusions, with p-values of 0.54 and 0.09, respectively, indicating no statistically significant difference.

A higher proportion of males in Group T (28%) required transfusions compared to females (4.3%), while in Group P, 7.1% of males and 26.5% of females needed transfusions. However, the p-values of 0.33 and 0.09 show no significant impact of gender on transfusion requirements in either group.

The residence status showed a more pronounced effect in Group P. Among rural participants, 80% required transfusions compared to only 37.5% in

Table 3: *Factors Influencing Transfusion Requirements in Group T and Group P*

	GROUP T		GROUP P		
	YES	NO	YES	NO	P VALUE
AGE					
20-30 YEARS	04 (22.2%)	14 (77.8%)	05 (29.4%)	12 (70.6%)	0.54
31-45 YEARS	04 (13.3%)	26 (86.7%)	05 (16.1%)	26 (83.9%)	0.09
Gender					
MALE	07 (28%)	18 (72%)	01 (7.1%)	13 (92.9%)	0.33
FEMALE	01 (4.3%)	22 (95.7%)	09 (26.5%)	25 (73.5%)	0.09
RESIDENCE STATUS					
URBAN	05 (12.5%)	35 (87.5%)	02 (5.3%)	36 (94.7%)	0.21
RURAL	03 (37.5%)	05 (62.5%)	08 (80%)	02 (20%)	0.01
OPERATIVE TIME					
≤ 120 MINUTES	07 (33.3%)	14 (66.7%)	02 (10.5%)	17 (89.5%)	0.05
> 120 MINUTES	01 (3.7%)	26 (96.3%)	08 (27.6%)	21 (72.4%)	0.21
OBESITY STATUS					
YES	05 (31.2%)	11 (68.8%)	02 (9.5%)	19 (90.5%)	0.01
NO	03 (9.4%)	29 (90.6%)	08 (29.6%)	19 (70.4%)	0.09

Group T, with a significant p-value of 0.01. Urban participants in both groups had lower transfusion requirements, but the difference was not statistically significant (p-value of 0.21). In Group T, 33.3% of procedures completed within 120 minutes required transfusions, while only 3.7% of procedures taking longer than 120 minutes needed transfusions. In Group P, 10.5% of operations under 120 minutes and 27.6% of those over 120 minutes required transfusions, with a p-value of 0.05 for the ≤ 120-minute category indicating a significant association.

Discussion

These data suggest that TXA may cure hemostatic disorders. Only 16.7% of TXA patients needed transfusions, a considerable decrease from the prior rate. In contrast, the placebo group had 20.8% more transfusions (p=0.01). This contrasts with the placebo group. This was one of the most surprising results of this experiment.[11] This discovery is noteworthy because blood infusions may cause transfusion reactions, immunosuppression, and infection. This research is interesting since blood transfusions have been linked to these results. Transfusion-free blood (TXA) improves therapeutic outcomes, saves medical expenses, and relieves resource strain. Reduce patient transfusion frequency to attain this goal.[12] Operations under 120 minutes were especially affected. The hemostatic effects of TXA are at their highest during the important intraoperative period, which may explain this result. This topic must be considered. These findings suggest that the TXA should be given at a time that suits the person to optimize its benefits.[13] This investigation also revealed TXA's safety, which was impressive. However, worries about thromboembolic complications have limited TXA's usage, especially in high-risk surgical situations. However, this trial found no significant increase in thromboembolic events in the TXA group. These findings support past evidence indicating TXA is safe at therapeutic levels.[14] Even if the outcomes are mostly encouraging, there are some limits. These restrictions must be \considered. The study was only done in one region and the sample size was tiny, thus the results may not be as applicable to a broader variety of scenarios as first thought. Even if the study took into consideration certain parameters that may increase the likelihood of misinterpretation, comorbidities and stone properties may still impact the results. This is true even though the research included several parameters. More multicenter trials with bigger sample numbers and longer follow-ups are needed to confirm these results and study TXA's long-term safety and effectiveness in PCNL. This is needed to meet the preceding sentence's criteria.[15] This study adds to the evidence that transfusion-induced thrombolysis (TXA) is an effective and safe way to control perioperative blood loss in PCNL settings. This research examined TXA's potential benefits. It is an important surgical adjuvant because it reduces transfusions and improves results. This is particularly true in high-risk groups. Future study should concentrate on improving dosing regimens and exploring how they might be utilized in more surgical situations to enhance patient care.[16]

Conclusion

This Quasi-Experimental Design of percutaneous nephrolithotomy (PCNL) patients shows that tranexamic acid (TXA) reduces blood loss and transfusions. This is because TXA reduces blood loss throughout the surgery. According to the data, TXA

caused less mean blood loss and required fewer transfusions than placebo. This was unlike the placebo group. The idea that TXA might help regulate blood loss during PCNL is given further attention after these findings. Because of this, patient safety and surgical results are improved. TXA consistently reduced these characteristics' risks across a broad variety of patient demographics. This happened despite the fact that residency status, weight, and operational time all affected transfusions. The fact that TXA did not increase unanticipated adverse events statistically is one of the most crucial results that proves this medicine is safe in this context. This crucial finding shows that this medicine is safe.

Conflict of Interest **None**

Funding Source **None**

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Authors Contribution

FK: Conceptualization of Project

MHK: Data Collection

MAS: Literature Search

MMA: Statistical Analysis

HAQ: Drafting, Revision

HBM: Writing of Manuscript